



ADMINISTRATIVE STAY OF ACTION

Roxane Laboratories Inc.'s ("Roxane's") request for a stay of the effective date of the approval of NDA 20-932 is found to be in the public interest and is hereby granted. This stay will remain in effect until such time as Roxane has submitted additional data and proposed revised labeling, and FDA has reviewed those data and has found that the drug covered by the application has been shown to be safe and effective under the conditions of use described in the revised labeling without reliance on investigations to which Roxane does not have a right of reference. Marketing under NDA 20-932 is prohibited during the pendency of the stay.

William K. Hubbard  
Senior Associate Commissioner for Policy,  
Planning, and Legislation

Dated: February 3, 2000

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